DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 20 1996

Re: DOMITOR® (4,670,455)
Docket No. 96E-0194

#17

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,670,455, filed by ORION-YHTYMA OY, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for DOMITOR®, the animal drug product claimed by the patent.

The total length of the review period for DOMITOR® is 4,000 days. Of this time, 2,294 days occurred during the testing phase and 1,706 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 512(j) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: April 8, 1985.

   FDA has verified the applicant's claim that April 8, 1985 was the date that the Investigational New Animal Drug application became effective.

2. The date the application was initially submitted with respect to the animal drug product under subsection 512(b) of the Federal Food, Drug, and Cosmetic Act: July 19, 1991.

   The applicant claims July 2, 1991, as the date the New Animal Drug Application (NADA) for DOMITOR® (NADA 140-999) was initially submitted. However, a review of FDA records reveals that the date of FDA's official acknowledgement letter assigning a number to the NADA was July 19, 1991, which is considered to be the initially submitted date for the NADA.

3. The date the application was approved: March 19, 1996.

   FDA has verified the applicant's claim that NADA 140-999 was approved on March 19, 1996.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Charles E. Van Horn
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